

### **REMARKS**

The applicants appreciate the examiner's review of the prior art and request reconsideration of the pending claims in view of the following remarks. Applicants previously added claims 93-110 and cancelled claims 1-36, 38, 39, 48, 50-62, 64, and 74-92. As discussed in greater detail below, Applicants have amended claims 37, 63, 93, and 102 to further refine the claimed invention. Accordingly, claims 37, 40-47, 49, 63, 65-73, and 93-110 are currently pending in the application.

### **Claim Amendments**

As mentioned above, to further refine the claimed invention, Applicants have amended independent claims 37, 63, 93, and 102. In particular, Applicants have amended claims 37, 63, 93, and 102 to include language that clarifies the contact between the gland member and the plug member. Each of the independent claims now include a plug member that has a "proximal end, a distal end, and *a distal section*" (emphasis added) and includes the limitation "the distal section of the plug member being the portion of the plug member distal to the opening." The gland member contacts the distal section of the plug member

Applicants do not feel that such amendments are required to overcome the prior art of record. Accordingly, Applicants would like to preserve their rights to pursue the prior claimed subject matter in a continuation application.

### **35 U.S.C. 102(b) Rejections**

The office action rejected claims 37, 40-47, 49, 63, 65-73, 93-110 under 35 USC 102(e) as being anticipated by US Patent Number 5,578,059 (Patzer, hereinafter "Patzer").

Claim 37 defines, in relevant part, a medical valve having a housing, a plug member, and a substantially flexible, resilient gland member secured to the housing and the plug member. The plug member is a cannula, defines a channel for directing fluid through the valve, and has an opening nearer to its distal end. The gland member normally occludes the opening and contacts the distal section of the plug member (e.g., the portion of the plug member distal to the opening).

Patzer fails to teach such a valve. Rather, Patzer teaches a anti-reflux valve with an environmental barrier. In particular, Patzer's valve has a series of connected housings (e.g.,

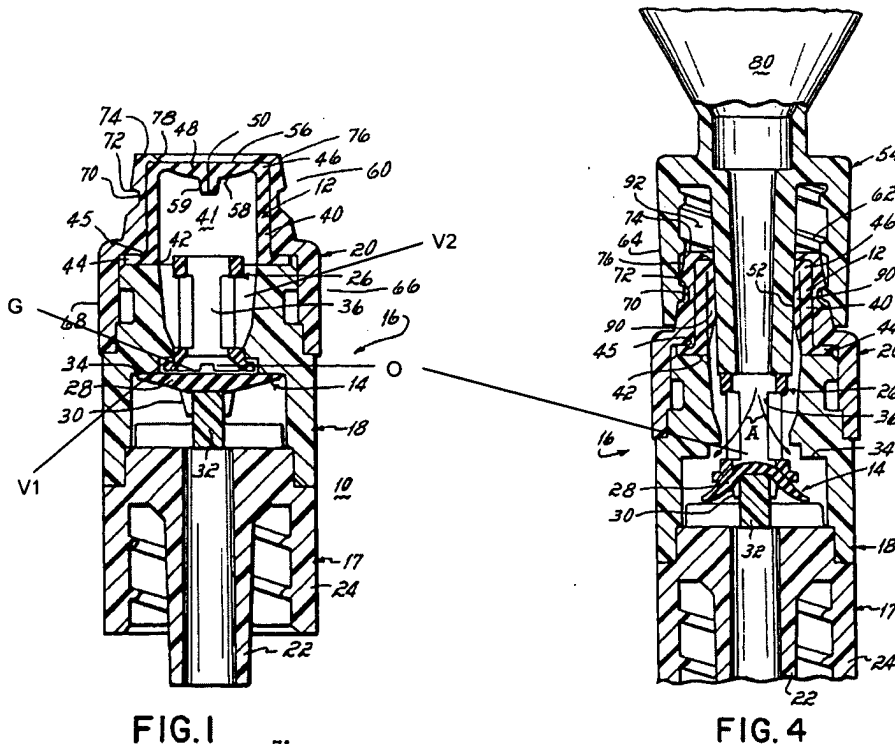
actuator housing 18, tapered thread housing 20, etc.), an actuator 26 and a disc valve 14. Patzer's disc valve 14 includes a resilient disc 28 and an underside skirt 30 that connects to a nipple 32 on the housing (i.e., luer lock connector 17). In operation, a taper 52 of a male luer 54 impacts against actuator 26 moving it downwardly into disc 28, causing the disc 28 to deform over the nipple 32 and open the valve (col. 4, lines 45-55, Fig. 4). Nowhere does Patzer teach or suggest a resilient member that is secured to both a housing and a plug member.

The Office Action suggests that Patzer's disc valve 14 constitutes the resilient gland member, that Patzer's actuator 26 constitutes the plug member, and that the disc valve 14 is secured to the housing (i.e., by nipple 32 of housing 17) and the plug member (i.e., as shown in Fig. 2). Applicants respectfully disagree. For the sake of argument, even if disc valve 14 could constitute the resilient gland member, Patzer's actuator 26 could constitute the plug member, and the disc valve 14 was secured to the housing (i.e., by nipple 32 of housing 17), Patzer's disc valve 14 is not secured to a plug member (e.g., actuator 26 according to the Office Action). In fact, as shown in Figure 1, there appears to be a gap (labeled as G on the figures 1 and 4 reproduced below) located between the disc valve 14 and the actuator 26. Additionally, as mentioned above, when a taper 52 of a luer 54 activates the valve, the luer 54 impacts the actuator 26 *moving it downwardly into disc 28*. It is clear from this passage that there is a gap between the actuator 26 and the disc 28 because the luer must move the actuator *downward into* the disc – had the actuator 26 and the disc 28 been secured to one another, there would be no need to move one component into the other.

Moreover, nowhere does Patzer teach or suggest a gland member that normally occludes an opening within a plug member, as required by amended claim 37. As mentioned above, the Office Action suggests that Patzer's disc valve 28 constitutes the resilient member and Patzer's actuator 26 constitutes the plug member. The office action also suggests that channel 36 extends through the actuator 26 such that actuator 26 has an opening (marked as O on the reproduced figure below) at the bottom (i.e., because the disc 28 deforms into the opening). However, even if this were true, Patzer's disc valve 28 does not normally occlude the opening. As known in the art, and as described in our responses dated December 12, 2008 and August 19, 2008, the term "occlude" means to close, or obstruct. Nothing in Patzer is closing or obstructing the channel 36 or opening O. Rather, as discussed above, the disc valve 28 is spaced from the bottom of the actuator 26 such that a gap (G in the reproduced Figures) is created between the disc valve 28

and actuator 26. This gap prevents the disc valve 28 from occluding the opening O and allows fluid and/or particulates to enter and exit the internal area of the actuator 28 from the volume between the actuator 26 and the disc valve 28 (e.g., volume V1 in the reproduced figures), and the volume surrounding the actuator 26 (e.g., volume V2 in the reproduced figure).

Furthermore, nowhere does Patzer teach or suggest a resilient member that normally contacts a distal section of the plug member (e.g., the portion distal to the opening). Rather, as described above, Patzer has a gap G between the disc valve 14 (which the office action suggests is the resilient member) and the actuator 26 (which the office action suggests is the plug member). This gap G prevents the disc valve 14 from normally contacting the distal section of the actuator 26. Accordingly, claim 37 is allowable over Patzer. Moreover, claims 40-47 and 49, which depend from claim 37 are allowable over Patzer for at least the same reasons discussed above for claim 37.



In a manner similar to claims 37, claims 63, 93, and 102 also define medical valves having resilient gland members that are secured to a housing and a plug member, normally occlude an opening within a plug member, and contacts a distal section of the plug member. Accordingly, claims 63, 93, and 102 are allowable over Patzer for the same reasons as discussed above with regard to claim 37. Moreover, claims 65-73, 94-101, and 103-110 which depend from claims 63, 93, and 102, are also allowable for at least the same reasons.

All pending claims therefore are allowable over the cited art. The application therefore is in condition for allowance and such action is earnestly solicited. Applicants do not believe that any extension of time is required. However, if an extension of time is required, Applicants hereby request that the associated fee and any additional fees required by this paper or credit any overpayment to Deposit Account No. 19-4972. Applicants also request that the examiner contact applicant's attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

Respectfully submitted,

/Jonathan C. Lovely, Reg. #60,821/  
Jonathan C. Lovely  
Reg. No. 60,821  
Tel: 617-443-9292